

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety & Risk Management Advisory Committee

DRAFT AGENDA

April 22, 2010

Agenda: The committees will discuss new drug application (NDA) 22-451 ACUROX (oxycodone HCl and niacin) Tablets, Acura Pharmaceuticals, Inc., for the proposed indication of relief of moderate to severe pain where the use of an immediate-release, orally administered, opioid analgesic tablet is appropriate, and the results of studies evaluating the addition of niacin, added for the purpose of reducing the misuse of oxycodone.

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| 8:00 a.m. | Call to Order Introduction of Committee | Chair, ALSDAC |
| | Conflict of Interest Statement | Kalyani Bhatt Designated Federal Officer, ALSDAC |
| 8:10 a.m. | Opening Remarks | Division of Anesthesia and Analgesia Products CDER/FDA |
| 8:15 a.m. | History of Prescription Drug Abuse in the US and "abuse-resistant" formulations | |
| 8:30 a.m. | Sponsor Presentations | |
| 10:00 a.m. | Break | |
| 10:15 a.m. | FDA Presentations | |
| 12:05 p.m. | Lunch | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | Questions for the Presenters | |
| 2:15 p.m. | Break | |
| 2:30 p.m. | Discussion and Questions to the Committee | |
| 4:30 p.m. | Adjourn | |